Mid-term cost-effectiveness analysis of open and endovascular repair for ruptured abdominal aortic aneurysm

K. E. Rollins, J. Shak, G. K. Ambler, T. Y. Tang, P. D. Hayes and J. R. Boyle

Cambridge Vascular Unit, Box 201, Level 6, Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge CB2 0QQ, UK

Correspondence to: Mr J. R. Boyle (e-mail: jonboyle@doctors.org.uk)

Background: Emergency endovascular repair (EVAR) for ruptured abdominal aortic aneurysm (rAAA) may have lower operative mortality rates than open surgical repair. Concerns remain that the early survival benefit after EVAR for rAAA may be offset by late reinterventions. The aim of this study was to compare reintervention rates and cost-effectiveness of EVAR and open repair for rAAA.

Methods A retrospective analysis was undertaken of patients with rAAA undergoing EVAR or open repair over 6 years. A health economic model developed for the cost-effectiveness of elective EVAR was used in the emergency setting.

Results: Sixty-two patients (mean age 77.9 years) underwent EVAR and 85 (mean age 75.9 years) had open repair of rAAA. Median follow-up was 42 and 39 months respectively. There was no significant difference in 30-day mortality rates after EVAR and open repair (18 and 26 per cent respectively; $P = 0.243$). Reintervention rates were also similar (32 and 31 per cent; $P = 0.701$). The mean cost per patient was €26 725 for EVAR and €30 297 for open repair, and the cost per life-year gained was €7906 and €9933 respectively ($P = 0.561$). Open repair had greater initial costs: longer procedural times (217 *versus* 178.5 min; $P < 0.001$) and intensive care stay (5.0 *versus* 1.0 days; $P = 0.015$). Conversely, EVAR had greater reintervention (€156 939 *versus* €35 335; $P = 0.001$) and surveillance ($P < 0.001$) costs.

Conclusion: There was no significant difference in reintervention rates after EVAR or open repair for rAAA. EVAR was as cost-effective at mid-term follow-up. The increased procedural costs of open repair are not outweighed by greater surveillance and reintervention costs after EVAR.

+A: Introduction

Emergency endovascular aneurysm repair (EVAR) is an accepted alternative treatment to traditional open surgical repair for ruptured abdominal aortic aneurysm (rAAA). In the short term, there is evidence that it has lower morbidity and mortality rates[1–3], and also shorter hospital stay, which may lead to lower perioperative costs. However, the recently published Amsterdam Acute Aneurysm (AJAX) trial[4] looking at open *versus* endovascular repair of rAAA in a multicentre randomized clinical trial demonstrated no significant difference in combined death or severe complication rates between the two treatments[4].

This institution[5] has previously published mid-term results following EVAR for rAAA, demonstrating favourable outcomes in a cohort of 52 patients, with sustained perioperative survival benefit compared with open repair for at least 2 years. The durability and efficacy of EVAR for elective abdominal aortic aneurysm (AAA) repair has been established in the long term[6,7]; however, this is not yet well known in the setting of emergency repair.

A cost-effectiveness analysis of EVAR *versus* emergency open repair for rAAA, based on a 22-study meta-analysis[8] demonstrated lower mean cumulative costs for EVAR. EVAR provided a greater number of quality-adjusted life-years (QALYs) in the emergency setting in the short term. The Open *Versus* Endovascular Repair (OVER) trial[9] randomized 881 elective patients to the two techniques; EVAR had lower initial costs and improved survival. However, there was no demonstrable difference in survival, quality of life or cost at 2 years following intervention. In contrast to this, a decision model using data mostly from the EVAR1 trial[10] calculated the long-term cost-effectiveness of EVAR *versus* open repair, and found EVAR to cost £3800 (€4535; exchange rate 8 December 2013) more per patient with fewer lifetime QALYs[11].

EVAR is associated with lower perioperative mortality than open repair for both elective[10] and emergency[12] treatment of AAA. There remain concerns surrounding increased surveillance costs[13] and also apparently higher reintervention rates, which may outweigh the early cost benefit[14]. There is currently little evidence in the emergency setting regarding the cost-effectiveness of either type of AAA repair at mid-term follow-up. This study used reporting standards[15] , defining short term as 30 days and 1 year following intervention, mid-term as greater than 2 years and long term beyond 5 years.

The aim of this study was to compare reintervention rates, mid-term outcome and cost-effectiveness in cohorts undergoing EVAR and open repair for rAAA.

+A: Methods

A retrospective analysis of a prospectively collated database was carried out on patients with rAAA presenting to Cambridge University Hospitals, a tertiary referral vascular unit in the

UK, between February 2006 when the database began and January 2012. Patients randomized to treatment as part of the Immediate Management of Patients with Ruptured Aneurysm: Open *Versus* Endovascular Repair (IMPROVE) trial[16,17] were included. The database was verified against electronic hospital records, including operative records, discharge and outpatient letters, imaging and blood transfusion records to ensure data were as complete and accurate as possible. This database included all patients with rAAA, defined as radiographic or intraoperative evidence of retroperitoneal or free intraperitoneal rupture. Site-specific ethical approval was granted for patients randomized within the IMPROVE trial. The study was registered with the Audit Department of Addenbrooke's Hospital.

Patients presenting with rAAA were managed using the principle of 'permissive hypotension', with transfusion of packed red blood cells and other transfusion products as necessary. The hospital has previously reported low palliation rates for patients presenting with rAAA[18]. The comparative costs of palliation for rAAA are not included in this analysis.

The choice of treatment for rAAA was based on surgeon's preference and aneurysm anatomy during the interval from commencement of the study until October 2009, beyond which the unit began randomization as part of the IMPROVE trial[11]. IMPROVE randomized patients with a clinical diagnosis of rAAA to either immediate transfer to theatre for open repair or computed tomography (CT) followed by EVAR if anatomically appropriate. All patients had rAAA confirmed by either CT or intraoperative evidence of rupture. EVAR was the treatment of choice in those deemed anatomically suitable both before the start of IMPROVE, or during this study for patients who were excluded from randomization. Usually this occurred because anatomical suitability had been established before recruitment. Five consultant vascular surgeons managed all patients, with roughly even proportions of each of the surgeons performing the two techniques. Those undergoing EVAR had insertion of either an aortouni-iliac device with a femorofemoral crossover, or a bifurcated graft, performed according to aneurysm anatomy, patient haemodynamic stability and surgeon preference.

During the whole study patients who had undergone EVAR returned to outpatients 6 weeks after discharge. They were then seen in a dedicated EVAR surveillance clinic at 6 and

12 months, and annually thereafter. Aortic CT was done after 3 and 12 months, followed by annual duplex imaging, plain abdominal X-ray and clinical review thereafter. Surveillance imaging recorded aneurysm size, the presence of endoleak, stent-graft migration and limb kinking or stenosis. CT beyond 12 months was used only for aneurysm enlargement or endoleak detected on duplex surveillance. Patients who had open repair were seen in outpatients at 6 weeks then 6 months, with no routine imaging, and then discharged unless further review was indicated clinically. Additional selective imaging was requested at the discretion of the operating surgeon.

+B: Cost-effectiveness analysis

The cost-effectiveness analysis was performed by summation of all costs for each group at two different time intervals – perioperative costs associated with the index admission, and those incurred as part of follow-up, including surveillance imaging and outpatient clinical review, as well as all reinterventions. *Table 1* details the cost assumptions used for this calculation, taken from the financial records of the institution. There were three levels of care: intensive care unit (ICU; level 2 and 3 beds), high-dependency unit (level 1 beds) and ward-based. There were different theatre costs for EVAR and open repair owing to the different staffing requirements for the two procedures, and these included heating, lighting, clean air, Private Finance Initiative repayments and theatre share of managerial costs. The cost of a stent-graft for EVAR was fixed at €5955 per case, irrespective of the number of stents or graft limbs used; this relatively low stent-graft cost reflects the high EVAR unit volume. In addition to this, a fee of €596 for needles, wires, sheaths, balloons and catheters required for EVAR was included in the analysis (ESSK-3 package; Cook Medical Europe, Limerick, Ireland). An overall cumulative cost for each group was calculated for both time intervals. The total number of days of follow-up, calculated as the number of days from hospital discharge following the index admission to either date of death or last note review, was then summated. A cost per day and year per patient following successful treatment was then calculated. All costs in this analysis were calculated in euros based on the exchange rate on 1 November 2013, which was €1.19099 per £1 GBP and quoted to the nearest euro.

Finally, incremental cost-effectiveness ratios (ICERs) were calculated, adopting a similar approach to that described previously[8]. As quality of life was not measured during follow-up, it was assumed to be similar to that following elective repair[19]. Quality-of-life data collected after the EVAR1 trial[20] were used to estimate the effect of treatment in QALYs. To account for reductions in quality of life in the immediate postintervention phase, it was assumed that reintervention caused similar short-term changes in quality of life.

+B: Statistical analysis

The data were analysed on an as-treated basis. This was an observational study, so crossover rates among those treated in IMPROVE were not assessed. Continuous variables are presented as mean(s.d.) or median (range). Unpaired *t* test was used for analysis of normally distributed continuous variables and Mann–Whitney *U* test for variables with a non-normal distribution. Pearson's χ^2 analysis and Fisher's exact test were used for binomial data. Overall survival and freedom from reintervention were analysed using Kaplan-Meier–plots, with significance of differences between the groups calculated by Mantel–Cox log rank test. All statistical analyses were two-sided and a significance level of $P < 0.050$ was set. Statistical analysis was undertaken using GraphPad Prism® version 5 (GraphPad Software, La Jolla, California, USA).

+A: Results

There were 147 patients included in the study. Sixty-two patients (mean 77.9 (56–97) years) underwent EVAR and 85 (75.9 (range 58–92) years) had open surgical repair for RAAA. The median follow-up was 42 (4–76) and 39 (2–75) months for EVAR and open repair respectively. Patient demographics were similar between the two treatment groups (*Table 2*). Overall there were 125 men (85.0 per cent) with a mean age of 77.2 (56–97) years.

Before the start of IMPROVE, 87 patients were included in the rAAA database (41 EVAR, 46 open repair) and 60 patients were added (21 EVAR, 39 open repair) following recruitment to IMPROVE. There was a bias towards open repair that explains the discrepancy in numbers between treatment methods, which had previously been roughly 50 per cent for each procedure[4]. Ten patients were not offered intervention for rAAA during the study interval. This low turn-down rate may not reflect that of the entire catchment population, as it may not include all patients with rAAA not referred from receiving hospitals.

+B: Outcomes

Some 33 (22.4 per cent) of 147 patients died within 30 days . There was no difference between EVAR and open repair (18 and 26 per cent respectively; $P = 0.243$). Similarly, mortality rates during follow-up were not significantly different (44 and 50 per cent respectively; $P = 0.697$).

Early reinterventions, required during the index admission, were significantly more common in the open repair group ($P = 0.002$), whereas the EVAR group had significantly more late interventions ($P = 0.008$) after discharge from the index admission (*Fig. 1*). There were 22 early reinterventions after open repair; these included six procedures for mesenteric ischaemia, two for perforated peptic ulcer and 14 revascularizations for ischaemic legs. There were four late reinterventions after open repair: two for adhesions, one aortocaval fistula repair and one aortoduodenal fistula repair. After EVAR there were only four early reinterventions, all related to femorofemoral bypass graft infection or leg ischaemia, There were 16 late reinterventions after EVAR, for aortic endoleak (7), stent-graft kinking (2), femorofemoral graft sepsis (2) and graft thrombosis (1). Overall rates of reintervention were similar in the two groups ($P = 0.701$).

Although there appeared to be an initial survival benefit in patients with rAAA treated by EVAR, there was no significant difference in overall survival rates for the two procedures ($P = 0.203$) and, in addition, no significant benefit at any time point following the intervention ($P = 0.357$) (*Fig. 2*).

+B: Cost-effectiveness analysis

The overall perioperative cumulative costs for the two procedures are detailed in *Table 3*. Costs were higher for open repair: €29 881 per patient compared with €24 194 for EVAR. The cost per patient treated successfully and discharged from hospital was also less in the EVAR group: €30 613 *versus* €42 332, a difference of €11 719 per patient.

Major factors influencing the perioperative cost included a significantly lower median ICU stay after EVAR (1.0 *versus* 5.0 days; $P = 0.015$) with a trend towards a shorter overall hospital stay (9.5 *versus* 15.0 days; $P = 0.268$). The median procedural duration was significantly lower for EVAR (178.5 *versus* 217 min; $P < 0.001$) as was the median amount of packed red cells transfused (3.5 *versus* 7 units; $P < 0.001$). Conversely the cost of stent-grafts, including femorofemoral crossover grafts, was significantly higher in the EVAR group.

Patients who had EVAR required significantly more follow-up appointments (median 2 (1–7) *versus* 1 (1–3); $P < 0.001$) and follow-up imaging (CT and ultrasound imaging:

median 2 *versus* 0 scans; $P < 0.001$). EVAR surveillance and reintervention costs were significantly higher, equating to an overall difference of €121 604 between the two procedures.

Overall costs for open repair and EVAR were similar ($P = 0.433$) (*Table 5*); EVAR was €3572 cheaper overall per patient and €2027 per year survived.

The mean QALY per patient during follow-up was 1.790 in the EVAR group compared with 1.355 in the open repair group. Duration of follow-up was similar in the two groups, so EVAR resulted in a gain of QALYs, with an ICER of approximately €–4933/QALY for EVAR compared with open repair, in favour of EVAR.

+A: Discussion

This study suggests that EVAR was as cost-effective as open surgical repair for rAAA for up to 3 years after intervention. Open repair was costly in the perioperative phase, whereas EVAR had increased follow-up and reintervention costs. EVAR was associated with lower mortality rates at both 30 days and at mid-term, but this survival advantage did not reach statistical significance. In the long term EVAR may become more expensive with increasing follow-up costs, as well as an increasing proportion of patients requiring reintervention. In addition, with the adoption of enhanced recovery programmes[21], it may be possible to reduce the perioperative costs of open repair.

Compared with the meta-analysis[8] of cost-effectiveness of open repair *versus* EVAR for rAAA, this study demonstrated higher overall costs per patient in both groups when converted to GBP (EVAR: £22 439 *versus* £17 422 in the meta-analysis; open repair £25 439 *versus* £18 930). These increases may reflect both a degree of inflation, but also the fact that the present study detailed actual costs, rather than the assumptions used in the meta-analysis. The costs incurred are specific to both the UK healthcare system and the Cambridge Vascular Unit, and so may not reflect costs elsewhere. In particular, the relatively low stent-graft costs reflect local negotiations in a high-volume elective EVAR unit.

The OVER trial[9] compared the cost-effectiveness of elective EVAR and open repair There was a significant difference in cost during the initial perioperative stay (US $37 068 *versus* $42 970; $P = 0.04$) (€27 069 *versus* €31 376; exchange rate 8 December 2013); however, at 2-year follow-up this difference was no longer significant ($5019 (€3665) difference; P = 0.35). Overall, the costs were higher for both techniques, reflecting higher healthcare costs in North America.

Clearly, an early death after intervention for rAAA conveys a cost reduction to the technique. The higher 30-day mortality rate after open repair should have reduced overall early costs of this procedure. Despite this, the perioperative costs were significantly higher after open repair, so the cost–benefit analysis may underestimate the early benefit of EVAR. Some increased costs of follow-up in the EVAR group may be acceptable given the reduction in 30-day mortality rates.

There are a number of limitations to this study. Before involvement in the IMPROVE study, patients with rAAA were offered EVAR if anatomically suitable. EVAR was still offered to some patients outside IMPROVE if they did not meet the inclusion criteria for the study (mainly patients in whom anatomical suitability for EVAR had been established by imaging at other hospitals before transfer). There may, therefore, have been selection bias before IMPROVE. This may be most relevant in patients deemed to have aneurysm anatomy unsuitable for EVAR. These patients have rAAAs that may be technically more challenging, requiring a suprarenal clamp during open repair, and potentially resulting in increased morbidity and mortality. Undertaking straightforward procedures with EVAR may create a selection bias, with more difficult cases undergoing open repair resulting in increased costs and reintervention rates in this group. Before IMPROVE, the majority of patients treated with open repair were anatomically unsuitable for EVAR. As a result, it was not possible to perform case matching in the present study. Dick and colleagues[22] have recently demonstrated, in the setting of open repair for rAAA, that anatomical suitability for EVAR is an independent predictor of survival[22]. Some also believe that EVAR is more likely to be offered to more stable patients, introducing further bias; this was not case in Cambridge[5]. In addition, there was no attempt to measure quality of life as part of the present study; the QALY calculations were based on results from other studies.

Follow-up after open repair is less rigorous than that following EVAR. Many potential reinterventions after open repair may not directly involve a vascular specialist, for example incisional hernia or adhesion-related bowel obstruction. This increases the possibility that reinterventions after open repair are under-reported, so follow-up and reintervention costs may be underestimated.

The accumulating number of reinterventions after EVAR with increasing follow-up raises concerns about the long-term durability of this technique for rAAA, and also longer-term cost-effectiveness. The excess rate of early reinterventions after open repair was overtaken by EVAR by 5 years of follow-up. Improving endograft systems to prevent late intervention would significantly change the cost balance between the techniques.

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Fig. 1 Freedom from reintervention after endovascular aneurysm repair (EVAR) *versus* open surgical repair of ruptured aortic aneurysm. Dotted lines represent 95 per cent confidence intervals. $P = 0.148$ (Mantel–Cox log rank test)

Fig. 2 Survival after endovascular aneurysm repair (EVAR) *versus* open surgical repair of ruptured aortic aneurysm. Dotted lines represent 95 per cent confidence intervals. There was no overall difference in survival between the two interventions ($P = 0.206$) nor benefit at any time point following intervention ($P = 0.357$) (Mantel–Cox log rank test)

Table 1 Unit cost assumptions for this hospital used to perform the cost-effectiveness analysis

	Cost (€)
Intensive care unit bed (1 day)	1429
High-dependency unit bed (1 day)	501
Ward bed (1 day)	395
Theatre time (1 h)	
EVAR	773
Open repair	788
EVAR graft	5955
EVAR disposables	596
Aortic tube graft	411
Femerofemoral crossover graft	250
Emergency department costs (0.5 h)	79
Packed red blood cells (1 unit)	146
Platelets (1 unit)	249
Outpatient appointment	170
Computed tomography of aorta	120
Duplex imaging of aorta	58

EVAR, endovascular aneurysm repair.

Table 2 Characteristics of 147 patients presenting with ruptured abdominal aortic aneurysm

	Whole cohort (n = 147)	EVAR (n = 62)	Open repair (n = 85)	P*
Mean(s.d.) age (years)	76.8(7.5)	77.9(7.0)	75.9(7.7)	0.104†
Sex ratio (M : F)	125 : 22	51 : 11	74 : 11	0.420
Ischaemic heart disease	65	27	38	0.889
Diabetes mellitus	8	5	3	0.282‡
Chronic kidney disease	9	3	6	0.734‡
Chronic obstructive pulmonary disease	29	11	18	0.605

EVAR, endovascular aneurysm repair. *χ^2 test, except †t test and ‡Fisher's exact test.

Table 3 Resource use and costs for perioperative care after endovascular or open repair for ruptured abdominal aortic aneurysm

	EVAR (*n* = 62)		Open repair (*n* = 85)		
	Resource use	Total cost (€)	Resource use	Total cost (€)	*P**
ICU stay (days)	319.5	456 566	897	1 281 813	0.015
HDU stay (days)	64	32 064	160	80 160	0.064
Ward stay (days)	1005	396 975	1840	726 800	0.268
Theatre time (h)	197	152 281	347	273 436	< 0.001
Packed red blood cells (units)	261	38 106	758	110 668	< 0.001
Platelets (units)	13	3237	100	24 900	< 0.001
Grafts	62	369 210	85	34 935	< 0.001
EVAR disposables	62	36 952	0	0	< 0.001
Femorofemoral crossover graft	39	9750	2	500	< 0.001
Emergency department (h)	31	4898	42.5	6715	1.000
Total cost		1 500 039		2 539 927	0.206

Cost of perioperative care included all costs associated with the index admission. EVAR, endovascular aneurysm repair; ICU, intensive care unit; HDU, high-dependency unit. *Comparison of costs (*t* test).

Table 4 Resource use and costs for follow-up and reintervention after endovascular or open repair for ruptured abdominal aortic aneurysm

	EVAR (n = 51)		Open repair (n = 63)		
	Resource use	Total cost (€)	Resource use	Total cost (€)	P*
Outpatient appointments	151	25 670	53	9010	< 0.001
Computed tomography	110	13 200	15	1800	< 0.001
Duplex imaging	17	986	0	0	< 0.001
ICU stay – reintervention (days)	12	17 148	5	7145	0.173
Ward stay – reintervention (days)	253	99 935	44	17 380	0.010
Total cost		156 939		35 335	0.001

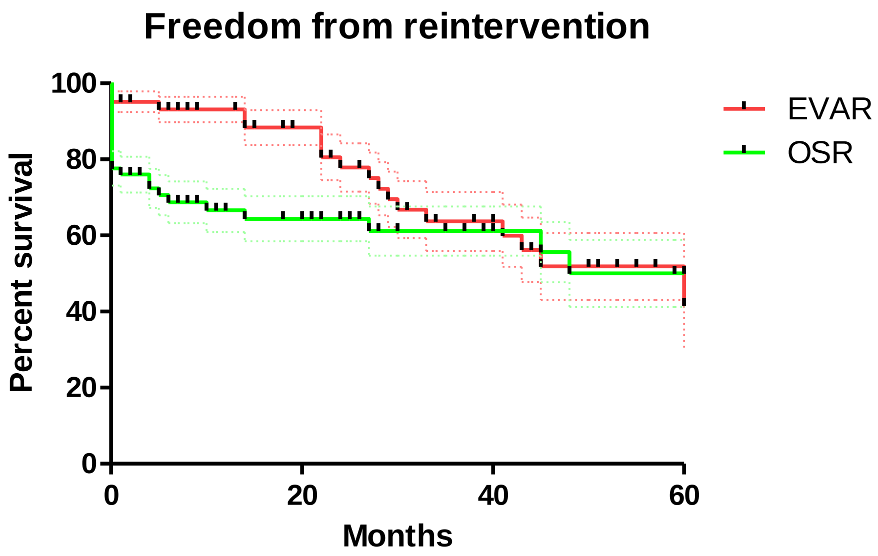
EVAR, endovascular aneurysm repair; ICU, intensive care unit. *Comparison of costs (t test).

Table 5 Overall costs

	EVAR (*n* = 62)	Open repair (*n* = 85)	*P**
Overall cost (€)	1 656 978	2 575 262	0.433
Mean cost per patient (€)	26 725	30 297	
No. of days of follow-up	76 495	94 635	
Cost per day of survival (€)	21.66	27.21	0.561
Cost per year of survival (€)	7906	9933	

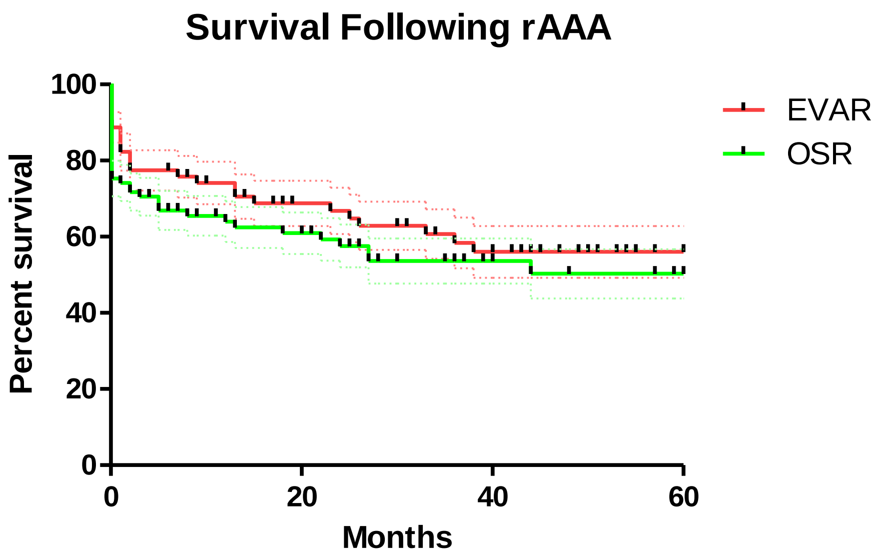
EVAR, endovascular aneurysm repair. **t* test.

Figure 1 –



	Months	0	10	20	30	40	50	60
Number at risk	EVAR	62	40	34	23	18	11	4
	OSR	85	42	36	22	15	11	9

Figure 2



	Months	0	10	20	30	40	50	60
Number at risk	EVAR	62	43	35	30	24	16	6
	OSR	85	44	39	24	17	14	10